DURASPHERE®
Injectable Bulking Agent

CE 0086

DIRECTIONS FOR USE

DESCRIPTION

Durasphere is a sterile, nonpyrogenic injectable bulking material composed of pyrolytic carbon coated beads suspended in a water based carrier gel containing beta glucan.

CONTENTS

1ml or 3ml syringe of Durasphere (to be used only with Durasphere Injection Needle).

MODE OF ACTION

Durasphere is injected sub-mucosally at the bladder neck in females and sub-mucosally at the level of the external sphincter in males. The injection of Durasphere creates increased tissue bulk and subsequent coaptation of the bladder neck and/or urethra. Over time collagen is deposited around the pyrolytic carbon coated beads. The final bulking result derives from the combination of the pyrolytic carbon coated beads and the body's own collagen.

INDICATIONS

Durasphere is intended for use only in the treatment of urinary incontinence due to stress incontinence, poor or nonfunctioning bladder outlet mechanism that may be helped by a locally injected bulking agent. Durasphere therapy should be initiated only in patients who have shown no improvement in their urinary incontinence for at least 12 months.

Durasphere is also intended for use in the treatment of vesicoureteral reflux when the patient's condition can be helped by a sub-ureteric injection of a bulking agent. Durasphere injection therapy should be initiated in vesicoureteral reflux patients who have failed more conservative management.

CONTRAINDICATIONS

Durasphere must not be used in patients with an acute condition involving cystitis, urethritis or infection.

WARNINGS

Durasphere should not be injected into blood vessels. Injection of Durasphere into blood vessels may cause vascular occlusion, infarction or embolic phenomena. Also, Durasphere may cause platelet aggregation if injected into blood vessels.

Durasphere should not be used in patients with bladder neck or urethral strictures until such strictures have been corrected.

PRECAUTIONS

The treatment procedure and instrumentation associated with the injection of Durasphere carry an inherent, yet minimal risk of infection and/or bleeding, as do similar urologic procedures. The usual precautions associated with urologic procedures, specifically cystoscopy, should be followed.

ADVERSE EVENTS

All patients can expect to experience some degree of dysuria, hematuria, urgency and frequency in the 24 hours immediately following injection of Durasphere. Most patients will have spontaneous resolution of these symptoms by the end of the 24 hours. Those who do not should contact their treating physician.

Some patients can expect to experience urinary retention as a result of Durasphere injection therapy. It can be managed by catheterization in the immediate post-injection phase and with clean intermittent catheterization should it persist. As a general rule, patients will be kept in the hospital or clinic where they receive their Durasphere injection until they are able to void on their own volition.

Adverse events associated with treatment may include but are not limited to: worsened incontinence; urinary retention; urinary tract infection; and/or localized responses (including swelling, erythema, induration, infection, necrosis, or abscess formation).

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Durasphere should not be used in patients with bladder neck or urethral strictures until such strictures have been corrected.

INSTRUCTIONS FOR USE

PRIOR TO USE

Durasphere is supplied steam sterilized in a sealed package and is intended for single use only. Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged in shipment. **DO NOT USE** if damaged. Immediately return damaged product to Carbon Medical Technologies.

The injection of Durasphere requires the following materials:

Durasphere Syringes

Durasphere Injection Needles

PROCEDURE - STRESS URINARY INCONTINENCE

1. Up to 10 ml of Durasphere may be injected into the sub-mucosal tissues of the urethra and/or bladder neck during a single injection procedure.
2. Using standard procedure, prepare the patient for cystoscopy. Insert a cystoscope (5.7 to 8.0 mm [17 to 24 Fr.]) with a minimum 1.7 mm (5 Fr.) working channel into the urethra.

Transurethral

3. Connect the Durasphere Syringe to the sterile Injection Needle and prime the needle. Advance the needle through the working channel of the cystoscope to the desired injection area. Do not inject Durasphere into blood vessels.
4. In women, advance the needle to a point approximately 1 to 1 1/2 centimeters distal to the bladder neck and insert the needle tip under the mucosa. Advance the needle tip one half centimeter under the mucosal lining and begin injecting Durasphere at the 6 o'clock position. A bleb should be visible under direct vision with the cystoscope. If a bleb does not appear, withdraw the needle and reposition more superficially. Inject again.
5. After a bleb has been raised by the injection of Durasphere, reposition the needle away from the initial injection site. Repeat injection procedure until the bladder neck is closed. The procedure typically will require between 4 to 6 ml of Durasphere.
6. In men, begin injecting at the most proximal portion of the external sphincter and work forward with subsequent injections. Since the procedure is dependent on causing the mucosal lining of the urethra and bladder neck to balloon up, the treating physician should look for viable mucosal lining.

GO TO STEP 7.

Periurethral

3. Connect the Durasphere Syringe to the sterile Injection Needle and prime the needle. Introduce the needle approximately 1 cm lateral to the urethral meatus.
4. Advance the needle through the perineum, parallel to the urethra, to the desired injection area (submucosal tissue of the proximal urethra). Proceed carefully during the injection procedure to avoid penetration of the urethral lining or bladder. Verify placement of the needle tip cystoscopically by gently moving the needle.
5. Inject Durasphere into the submucosal tissue until unilateral or circumferential closure is seen.
   - If circumferential flow of material is being observed, continue injecting until complete coaptation of the bladder neck is seen with cystoscopic irrigation fluid on. Remove the injection needle.
   - If unilateral closure is observed, continue injecting until the submucosal tissue crosses the midline of the urethra. Remove the injection needle and repeat on the opposing side. Inject at the second location until coaptation of the bladder neck is seen with cystoscopic irrigation fluid on. Remove the injection needle.
6. Since the procedure is dependent on causing the mucosal lining of the bladder neck to balloon up, the treating physician should look for viable mucosal lining.

7. The physician may continue to use the Injection Needle and connect new Durasphere syringes to it or can use a new needle with each syringe of Durasphere.

PROCEDURE - VESICOURETERAL REFLUX

1. Routine cystoscopy is performed and the ureters are visualized.
2. Connect the Durasphere Syringe to the sterile cystoscopic injection needle and prime the needle. Advance the needle through the working channel of the cystoscope.
3. The needle tip is inserted at the 6 o'clock position into the subureteric space approximately 4 to 6 mm distal to the ureteral orifice. The needle tip is advanced into the submucosal space directly underneath the orifice. The bulking agent is injected under direct visualization until a bulge nearly obliterates the ureteral orifice (the standard STING procedure). The orifice after successful injection has an inverted crescent appearance.
4. The needle can be held in place for a period of time after injection to avoid loss of bulking material.

NOTE: If the injection needle is inserted into muscle rather than submucosal tissue, the Durasphere beads will not flow because muscle is too dense to accept the beads. The Durasphere gel will flow into muscle under extreme force. If this happens, Durasphere beads will clog the injection needle.

After use, treatment syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

If the problem persists after initial injection or if improvement is followed by recurrence of symptoms, treatment may be repeated after sufficient time has passed to evaluate prior to retreatment but in no case shall the patient be retreated within 7 days of previous treatment.

HOW SUPPLIED

Durasphere is provided in individually packaged 1 ml or 3ml syringes. The contents of Durasphere syringes are sterile and nonpyrogenic.

Do not use open or damaged packages; return to Carbon Medical Technologies for replacement. Do not use if packaging is not intact or if the syringes or needles appear to be damaged.

The Durasphere system consists of:

Product	Contents	Appropriate Needle(s)
Durasphere 1ml syringe Catalog # 030965	Approximately 1ml of Durasphere Injectable Bulking Agent	Any Durasphere Injection Needle

Contraindication: The use of Durasphere with needles other than those recommended in this DFU may result in Durasphere beads clogging the injection needle.

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The injection needle, injectable bulking agent, packaging, syringe, and syringe components are all latex free.

STORAGE

There are no unusual storage instructions for the Durasphere or Injection Needles. The products should be at room temperatures, 15 °C - 32 °C (59 °F - 90 °F), prior to use.

Do not resterilize. Unless the packaging is damaged, the Durasphere and Injection Needles will remain sterile until used.

Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

WARNING

For single use only. DO NOT REUSE, REPROCESS OR RESTERILIZE. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

WARRANTY

Carbon Medical Technologies warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling and storage of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Carbon Medical Technologies' control directly affect the device and the results obtained from its use. Carbon Medical Technologies' obligation under this warranty is limited to the replacement of this device and Carbon Medical Technologies shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Carbon Medical Technologies neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Prices, specifications and model availability are subject to change without notice.

Durasphere is a trademark of Carbon Medical Technologies, Inc.

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